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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,362	11/30/2004	Henrik H. De Nijs	O-2002-732 US	5594

67706 7590 09/15/2008

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EXAMINER	
JEAN-LOUIS, SAMIRA JM	

ART UNIT	PAPER NUMBER
1617	

NOTIFICATION DATE	DELIVERY MODE
09/15/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/517,362	DE NIJS ET AL.	
	Examiner	Art Unit	
	SAMIRA JEAN-LOUIS	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-41* is/are pending in the application.

4a) Of the above claim(s) *37-41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/30/04, 08/07/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Examiner for this current application at the USPTO has been changed.

Examiner Samira Jean-Louis can be reached at 571-270-3503.

Election/Restrictions

Claims 32-41 are currently pending in the application.

Applicant's election with traverse to various groups in the reply filed on 05/21/08 is acknowledged. The traversal is on the ground(s) that the claims relate to a single general inventive concept. This is not found persuasive because the claims recited in the instant application recite species that are known in the art and therefore render the invention not related to a single general inventive concept and consequently results in a lack of unity of invention. Thus, in this instance, these groups are patentably distinct and fully capable of supporting separate patents and furthermore may raise different non-prior art issues. Moreover, the search would indeed be unduly extensive and burdensome given that a search for these groups would consist of searching multiple databases for various references and literature searches.

Thus, the requirement is still deemed proper and is therefore made FINAL.

Claims 37-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d) for foreign priority based on an application filed in Germany on 05/302002, which papers have been placed of record in the file.

IDS

The information disclosure statement filed on August 07, 2007 (specifically items 1 and 4) and the information disclosure statement filed on November 30, 2004 (specifically item DE 42 40 806 A1) fail to comply with 37 CFR 1.98(a)(3) because they do not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. They have been placed in the application file, but only the information referred to therein in the English abstracts has been considered.

Provisional Non-Statutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 32 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 4 of U.S. Patent 7,323,454 B2 (hereinafter DeNijs US Patent Application No. '454). Although the conflicting claims are not completely identical, they are not patentably distinct from each other because both applications are directed to a composition comprising a therapeutically effective amount

of etonogestrel undecanoate, and/or etonogestrel decanoate, and/or etonogestrel dodecanoate). The claimed invention and co-pending application DeNijs '454 are rendered obvious over another as the claimed invention teaches the subgenus of an oily pharmaceutical composition comprising esters of etonogestrel whereas DeNijs '454 teaches the broad genus of a kit which contains the pharmaceutical composition comprising esters of etonogestrel. Thus, the aforementioned claim of the instant application is substantially overlapping in scope as discussed hereinabove and is prima facie obvious over the cited claim of corresponding application No. 10/517362.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

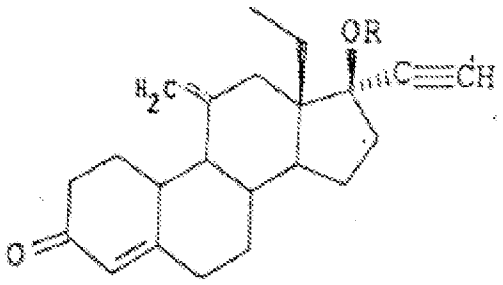
> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 32 and 34 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Lip et al. (ZA 96/06083, cited by applicant and filed on an IDS 1449).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Lipp et al. teach agents for transdermal administration, which is characterized in that it contains progestogen esters of 13-ethyl-17ß-hydroxy-11-methylene-18,19-dinor-17α-pregn-4-en-20-yn-3-one having 1 to 20 carbon atoms in the ester radical, optionally in combination with one or more oestrogen (s) (instant claims 32; see pg. 1, paragraph 1, pg. 2, paragraphs 2-3, and pg. 3, last paragraph). The aforementioned esters possess the following structural formula:



wherein R is an acyl radical having from 1 to 20 carbon atoms (see pg. 1, paragraph 2-3). For the manufacture of pharmaceutical preparations, the active ingredient mixture may be dissolved or suspended in suitable volatile solvents and/or penetration-enhancing agents (see pg. 4, paragraph 2). Suitable penetration-enhancing agents include fatty alcohols having 8 to 18 carbons atoms such as lauryl alcohol, or cetyl

alcohol, or hydrocarbons such as mineral oil (see pg. 4, last paragraph and pg. 5, paragraph 1). The concentration in which the active ingredient mixture is optimally dissolved or suspended is usually from 01.01 to 40% or up to 50% by weight for the etonogestrel esters (see pg. 5, last paragraph and pg. 10, paragraph 4). For example the daily dose can be approximately from 40 to 150 µg (see pg. 6, paragraph 2).

Lipp et al. do not specifically teach a composition where the etonogestrel esters are in the amount of 25-200 mg or a composition comprising specifically etonogestrel undecanoate and/or etonogestrel decanoate or etonogestrel dodecanoate.

Lipp et al., however, do teach etonogestrel esters containing 1 to 20 carbons which necessarily include decanoate esters (i.e. 10 carbons), undecanoate esters (i.e. 11 carbons), and dodecanoate esters (i.e. 12 carbons).

Moreover, Lipp et al. do not disclose the exact dosage of the etonogestrel esters. However, it is well within the purview of the skill of the artisan at the time of the invention to adjust the concentration and range of the etonogestrel esters so as to obtain the desirable dosage efficacy.

Moreover, it is generally noted that differences in concentration do not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or dosage is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ

233, 235 (CCPA 1955). Given that applicant did not point out the criticality of specific ranges or dosages of the invention, it is concluded that the normal desire of scientists or artisans to improve upon what is already generally known would provide the motivation to determine where in a disclosed set of ranges is the optimum combination of dosages.

Claims 33, 35, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lip et al. (ZA 96/06083, cited by applicant and filed on an IDS 1449) as applied to claims 32 and 34 above and in further view of Leysen et al. (WO 99/67271, cited by applicant and filed on an IDS 1449).

The Lipp et al. reference is as discussed above and incorporated by reference herein. However, Lipp et al. do not address addition of an androgen ester to the composition.

Leysen et al. teach MENT undecanoate as a novel androgen with good solubility in oily media and good dissolved potency relative to testosterone that is suitable for administration by means of injection (instant claims 33 and 35; see abstract). Leysen et al. further teach that androgenic hormones are typically administered for male contraception and hormone replacement therapy (HRT) and typically involves addition of a progestagen which serves to achieve a contraceptive effect and an androgen that serves to supplement the resulting decreased testosterone level (see pg. 1, lines 18-22 and see pg. 8, claims 5-6). Importantly, Leysen et al. teach that a need therefore exists

for low frequency administration where the androgen needs to be administered in a soluble solution via injection (see pg. 1, lines 25-31). As for the dosage of the MENT undecanoate, Leysen et al. teach that the amount administered will depend on the therapeutic effect, route of administration, age and condition of the individual subject and particular regimen to be followed (see pg. 4, lines 27-31). Leysen et al. particularly teach that MENT undecanoate can be administered in a range between 50-250 mg (instant claim 36; see pg. 5, lines 1-2).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to add MENT undecanoate since Leysen et al. teach that addition of MENT undecanoate to progestin-esters containing compositions serves to supplement the resulting decreased testosterone level and that MENT undecanoate can be effectively given as an Injectable solution. Given the teachings of Lipp and Leysen, one of ordinary skill would have been motivated to add MENT undecanoate to the composition of Lipp et al. with the reasonable expectation of providing a composition that is efficacious in treating HRT and easily administered as an injection.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-6 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. L. /

Examiner, Art Unit 1617

08/26/2008

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617